

# PATENT COOPERATION TREATY

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### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LPB/P100303WO		<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/GB2004/000239		International filing date (day/month/year) 23.01.2004		Priority date (day/month/year) 23.01.2003
International Patent Classification (IPC) or national classification and IPC A61K31/715, A61K47/12, A61P31/12				
Applicant ML LABORATORIES PLC et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 5 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in Item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 16.11.2004		Date of completion of this report 28.04.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Collura, A Telephone No. +49 89 2399-7870 		

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/000239

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-18 received on 17.11.2004 with letter of 16.11.2004

**Claims, Numbers**

1-44 filed with telefax on 11.04.2005

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

\* *If item 4 applies, some or all of these sheets may be marked "superseded."*

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/000239

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-44
	No: Claims	
Inventive step (IS)	Yes: Claims	1-44
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-44
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: EP-B-0 394 333 (BUKH MEDITEC) 31 October 1990 (1990-10-31)
- D2: STAFFORD M K ET AL: "A PLACEBO-CONTROLLED, DOUBLE-BLIND PROSPECTIVE STUDY IN HEALTHY FEMALE VOLUNTEERS OF DEXTRIN SULPHATE GEL" JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROMES AND HUMAN RETROVIROLOGY, LIPPINCOT-RAVEN, XX, vol. 14, no. 3, 1 March 1997 (1997-03-01), pages 213-218, XP001095808 ISSN: 1077-9450
- D3: WO 92/04904 A (ML LAB PLC) 2 April 1992 (1992-04-02)
- D4: EP-A-0 240 098 (UENO SEIYAKU OYO KENKYUJO KK) 7 October 1987 (1987-10-07)
- D5: MCCORMACK S ET AL: "MICROBICIDES IN HIV PREVENTION" BMJ. BRITISH MEDICAL JOURNAL, LONDON, GB, vol. 322, no. 7283, 17 February 2001 (2001-02-17), pages 410-413, XP001145843 ISSN: 0959-8146
- D6: CHIRIFE J ET AL: "Effect of potassium sorbate and pH on the survival of Staphylococcus aureus in saturated sugar solutions." REVISTA ARGENTINA DE MICROBIOLOGIA. 1993 APR-JUN, vol. 25, no. 2, April 1993 (1993-04), pages 80-87, XP009031004 ISSN: 0325-7541
- D7: US 2002/173485 A1 (BRAGUTI GIANLUCA ET AL) 21 November 2002 (2002-11-21)

The document D2 is regarded as being the closest prior art to the subject-matter of claim 1, and shows a pharmaceutical gel formulation comprising dextrin sulphate and lactic acid to be applied on mucosae for decreasing the risk of contracting sexually transmitted diseases and, in particular AIDS.

The subject-matter of claim 1 differs from this known D2 in that sorbic acid or a salt thereof is added to the formulation as a preservative.

The subject-matter of claim 1, therefore, appears to be new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as the provision of a preservative system for polyglucose compositions (in particular dextrine sulphate) with a broad spectrum of activity against a wide range of bacteria and fungi which avoids or mitigates the possibility of disrupting the healthy vaginal microflora (see description, page 3, second par.)

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) because, although sorbic acid and its salts are known as preservative agents (D1, D6 and D7), it is not suggested, by the available prior art, to use sorbic acid or its salts in combination with polyglucose in order to achieve both the preservation of the formulation and the maintenance of a healthy vaginal microflora.

Claims 2-34, which are dependent on claim 1, and claims 35-44 which are the corresponding use claims also meet the requirements of the PCT with respect to novelty and inventive step.